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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,216	02/02/2001	James G. Morris	6829/60165 (800189-05)	1182

7590 10/20/2003

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,216	MORRIS ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-4,28,29,31,32,34 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-27,30,33 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is in response to Paper No. 7, filed 28 July 2003, wherein Applicants elected Group II, claims 5-27, 30, 33 and 35. Claims 1-36 are currently pending with claims 5-27, 30, 33 and 35 under consideration.

Applicant's election of Group II, claims 5-27, 30, 33 and 35 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The present application claims partial priority as a Continuation-in-Part of Application Serial No. 09/501,548, filed 09 February 2000, in the Cross-Reference section. The Office records show that the previous application is abandoned. Applicants are required to update the cross-reference section of the present application regarding the status of any priority applications.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8-27, 30, 33 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rejected for the indefinite recitation of the phrase "providing for the genetic potential" wherein it is unclear if the cat had the potential and lost it or if the cat never had it. Furthermore, there is no method of measuring a cat's potential for hair melanin synthesis. Applicants should consider amending the claim to recite, i.e., --A method of promoting in a cat the synthesis of hair melanin by...--

Claim 8 is rejected for the indefinite recitation of the phrase of "providing" a cat, wherein it is unclear whether the cat is a patient/subject or if the cat is a key component.

Claims 9-15 and 30 are rejected for the indefinite recitation of the phrase "more than about" wherein the term is vague as to what the lower limit is. "More than about", for example, suggests that when requiring "more than about 0.80% by weight" that one could use 0.78% by weight since "about" could mean 0.77% and by the breadth of the claims 0.78% is more than 0.77% which about 0.88% by weight. Applicants should consider deleting either "about" or "more" from the claims.

Claims 16-27 are rejected for depending from rejected claims.

Claims 30 and 33 are rejected for the indefinite recitation of the phrase "allowing expression of the genetic potential", wherein it is unclear how one would allow expression of the genetic potential. The disclosure does not define "allowing" or "potential". Can the cat at this point decide not to express the genetic potential? Is the expression promoted or induced by the nutritional diet or does the diet just provide the "potential" for which the cat may or may not act?

Claim 35 is rejected for the indefinite recitation of the phrase "therapeutically effective amount", wherein it is unclear what the amount is and what therapeutic effect is sought.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5-27, 30, 33 and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of maintaining or restoring hair color in cats and dogs, does not reasonably provide enablement for methods of maintaining or restoring hair color in humans or other animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C.

112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a method for maintaining or restoring hair color in animals, comprising administering a consumable product containing particular proportions of tyrosine and/or phenylalanine. The term "animal" encompasses humans, as well as non-mammalian animals which do not have hair.

The state of the prior art and the predictability or lack thereof in the art: The art teaches the use of such methods for the treatment of dogs and cats, however, there is no prior art that teaches methods of using a consumable food supplement as a systemic treatment to maintain or restore hair color in humans. Thus, there is no predictability within the art that would for a nexus between systemic hair color modulation in cats and humans. WO 01/32030 A1 teaches the use of such methods for modulation or maintenance of **fur** for cats, however, there are no teachings of the methods for systemic treatment of human hair color based on consumable food supplements for cats and/or dogs.

The amount of direction or guidance present and the presence or absence of working examples: Given the lack of teachings for predictability found in the art, detailed teachings are required to be present in the disclosure in order for the skilled artisan to be able to systemically

maintain or restore hair color in humans by using methods that are for the treatment of cats. These teachings are absent. The teachings found in the present specification are limited to general statements that the method of the invention may be employed to maintain and restore hair color in humans and other animals and working examples describing only how to maintain and/or restore hair color in black cats. There are no teachings and no guidance in the disclosure addressing how to systemically maintain and/or restore hair color in humans or in animals other than black cats. There are no working examples describing either maintenance or restoration of hair color in humans or animals other than black cats.

The breadth of the claims and the quantity of experimentation needed: Because the art does not teach the systemic restoration and maintenance of hair color for humans, it is extremely unpredictable and may actually have a deleterious effect upon both therapeutic efficacy and drug toxicity, and because the disclosure is devoid of any teachings or guidance as to how to overcome the lack of teachings for predictability, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
15 October 2003

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600